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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/711,648	11/13/2000	Dean M. Ponzi	37646/KMO/W112	7874
23363	7590	06/13/2005	EXAMINER	
CHRISTIE, PARKER & HALE, LLP			SIRMONS, KEVIN C	
PO BOX 7068				
PASADENA, CA 91109-7068			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 06/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/711,648

Applicant(s)

PONZI ET AL.

Examiner

Kevin C. Sirmons

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-35 and 39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21, 23-35 and 39 is/are rejected.
- 7) ☒ Claim(s) 22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/20/00</u> | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5-12, 17-20, 23, 27, 28, 32, 33 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al U.S. Pat. No. 5,435,805 in view of Gough et al U.S. Pat. No. 5,810,804.

Edwards discloses an injection catheter comprising: a catheter body comprising a flexible tubing having proximal and distal ends and at least one lumen therethrough (2); a tip section comprising a flexible tubing having proximal and distal ends, wherein the proximal end of the tip section is mounted at the distal end of the catheter body (figs. 15-23); a needle control handle at the proximal end of the catheter body (figs. 1 and 24); an injection needle extending through the tip section, catheter body, and needle control handle and having proximal end attached to the needle control handle and a distal end within the tip section, wherein the injection needle is longitudinally slidable within the tip section so that its distal end can extend out the distal end of the catheter upon suitable manipulation of the needle control handle (col. 6 and figs. 1 and 24); and an electrode lead wire having a first end electrically connected to the injection needle and a second end electrically connected to a suitable monitoring apparatus or to a source of ablation energy (figs. 1, 24 and the entire specification).

Edwards does not disclose a penetration-monitoring electrode mounted on the injection needle. Gough discloses a penetration-monitoring electrode mounted on the injection needle (28, 30, 32). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Edwards to include the penetration-monitoring electrode as taught by Gough for monitoring the temperature at various points within the interior of selected tissue mass, so that a determination of the selected tissue mass periphery can be made (col. 4). Note: The electrode of Gough measures impedance at various sites within the body just as applicant's electrode measures impedance at various sites within the body (applicant's specification page 4). As to claims 5-8, (see above listed figures and fig. 23); as to claims 23, 27 and 28 (see above rejection); as to claims 11, 12, (Edwards fig. 23 and Gough fig. 1); as to claims 17-20, 32, 33 (Edwards fig. 23 and (Gough fig. 1 and col. 4)).

Claims 2-4 and 24-26 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Edwards et al U.S. Pat. No. 5,435,805.

Edwards discloses an injection catheter substantially as claimed however, it may not be clear to someone who is not of ordinary skill in the art that the that the first end of the electrode lead wire is connected near the proximal end or distal end of the injection needle; or the number of wire or material. Therefore, it is the position of the examiner that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have a proximal and/or distal wire connection, since it has been held that rearranging parts of an invention involves only routine skill in the art.

In re Japikse, 86 USPQ 70. As to claims 4 and 26, (col. 42-63). Furthermore, the materials and number of wires are regarded as obvious to one having ordinary skill in the art (see fig. 1 for lead wires), since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claims 21 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards U.S. Pat. No. 5,435,805.

Edwards discloses an injection catheter substantially as claimed except for wherein the injection needle extends distally beyond the distal end of the tip section in a direction generally parallel to the axis of the catheter body. It would have been an obvious matter of design choice to change the shape of the tip section so that the injection needle can be parallel to the axis of the catheter body, since a modification would have involved a mere change in the shape of a component. A change in shape is generally recognized as being within the level of ordinary skill in the art. In re Daily, 357 F. 2d

Claims 12-16, 30, 31, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards U.S. Pat. No. 5,435,805 in view of Edwards U.S. Pat. No. 5,599,294 and further in view of Edwards 5,370,675.

Edward discloses an injection catheter substantially as claimed except for disclosing a method for introducing a therapeutic or diagnostic agent into heart tissue of a patient and the limitations of claims 13, 15 and 16.

Edwards discloses a method of using an injection catheter for introducing therapeutic or diagnostic agent into the heart tissue of a patient (Edwards '294' col. 5). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use Edwards device in the heart since Edwards (294) discloses that it would be readily apparent to a person skilled in the art that the device and method can be used to destroy body tissues in areas other than the prostate such as the brain, heart and/or other body cavities and tissue locations that are accessible by percutaneous or endoscopic catheters. Application of the device and method in all of these organs and tissues are intended to be included within the scope of this invention. As to claims 13 and 15, (Edwards '675'; col. 13, lines 5-18) and (col. 14, lines 1-11); as to claim 14, (Edwards '805' and see above rejection); as to claim 16, (Edwards '675' col. 3); as to claims 30, 31, 34, 35 (see above rejections).

#### ***Allowable Subject Matter***

Claim 22 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin C. Sirmons whose telephone number is 571-272-4965. The examiner can normally be reached on Monday-Friday 6:30-4:00 ALT FRI.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).



Kevin C. Sirmons  
Primary Examiner  
Art Unit 3763

6/8/05